DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/3/12 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 14, 17 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kline (Pub. No.: US 2004/0210154) in view of Fishman (US Pat: 5,271,401) and further in view of Griffith et al (US Pat: 6,197,575) and further in view of Liu et al (Noninvasive investigation of blood oxygenation dynamics of tumors by near-infrared spectroscopy).

Regarding claims 14 and 21-22, Kline discloses means for administering carbon dioxide and oxygen into the lung [see figs 1-4, 0042-0047] and lasers operating in the near infrared [see 0055] to illuminate the lung. Kline discloses laser diode spectrometry can be used for detection of more than one gas and can be used for determining the

presence of various pathophysiological processes that are specific to certain disease states and diagnosing the presence of lung cancer [see 0026, 0057 and abstract]. Kline discloses in an attempt to increase the accuracy of diagnostic, physicians have recently turned to methods which can produce an image of a potentially afflicted lung which involves the injection of a small amount of radioactive particles into a vein. The radioactive particles then travel to the lungs where they highlight the perfusion of blood in the lung based upon whether they can penetrate a given area of the lung. While normal results can indicate that a patient lacks a pulmonary embolism [see 0010]. Kline discloses data processing means determines the oxygen and carbon dioxide concentrations and a display screen to diagnose embolism [see 0026, see fig 11 and 0063-0064].

Kline doesn't explicitly mention varying the levels of carbon dioxide and oxygen.

Nonetheless, Fishman discloses administer a mixture of gases such as oxygen and carbon dioxide [see column 7 lines 20-43]; using an imaging system to image the patient during and before administering the gas mixture [see column 7 lines 45-65, column 8 lines 1-15]. Fishman also discloses varying the percentage of each gas in the mixture [see column 8 lines 32-36].

In addition, Griffith et al disclose an oxygenator 187 which supplies oxygen and removes carbon dioxide. The flow rate of inlet gas can be controlled through the use of a control valve 192 connected to a computer control system 183 [see column 30 lines 53-68, column 31 lines 1-3 and fig 7 and 11].

Furthermore, Liu et al disclose varying the level of carbon dioxide and oxygen [see page 5232, middle right column]; using the breast (human tissue) [see page 5234, lower right side, page 5232, upper left column]; NIR instrument to measure oxygen concentration in the vasculature [see page 5238, lower right column, page 5239, middle right column] and in vivo imaging [see introduction, page 5232, middle left column] and vascular bed of the breast and prostate in rats (animal tissue) [see page 5232, middle left column].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine with Liu et al and Griffith et al by using the control valve along with the oxygenator to vary the levels of carbon dioxide and oxygen in vivo within human or animal tissue and with Fishman by using the imaging system to acquire images of the region of interest before and during administration of the gas and use the data analyzer of Kline which includes computer processor to analyze the image for identifying diseases such as vascular cancer; in order to provide an accurate and reliable diagnosis.

Regarding claim 17, all other limitations are taught as set forth by the above teaching.

Kline discloses using multiple light emitting diodes [see 0057, 0061]. Kline discloses in the near infrared range, detection wavelengths will be 1390 nm for carbon dioxide and 760 nm for oxygen [see 0056]. Wavelengths of 780, 840 and 970 are

possible wavelengths that can be used; however, any other wavelengths can be used as long as there are within the near infrared range.

4. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over over Kline (Pub. No.: US 2004/0210154) in view of Fishman (US Pat: 5,271,401) and further in view of Griffith et al (US Pat: 6,197,575) and further in view of Liu et al (Noninvasive investigation of blood oxygenation dynamics of tumors by near-infrared spectroscopy) as applied to claim 14 above and further in view of Parker et al (US Pat: 5,548,120).

Regarding claim 16, all other limitations are taught as set forth by the above teaching.

Kline doesn't teach a charge coupled camera sensitive in near infrared.

Nonetheless, Parker et al disclose CCD image camera that is sensitive in infrared illumination [see fig 1, column 3 lines 1-5, lines 66-68 and column 4 lines 1-5].

Therefore, one skilled in the art at the time the invention was made would have been motivated to combine Kline with Parker et al by using a camera sensitive in near infrared; because using near infrared because it's highly sensitive for tumor/cancer detection and tracking.

5. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being over over Kline (Pub. No.: US 2004/0210154) in view of Fishman (US Pat: 5,271,401) and further in view of Griffith et al (US Pat: 6,197,575) and further in view of Liu et al (Noninvasive investigation of blood oxygenation dynamics of tumors by near-infrared spectroscopy)

as applied to claim 14 above and further in view of Dolecek et al (Pub. No.: US 2004/0058794).

Regarding claims 18-20, all other limitations are taught as set forth by the above teaching.

Kline doesn't teach a holding means containing an immersion medium or tissue phantom liquid having optical properties of the region of interest and a doughnut-shaped transparent bag that can be pressed against the region of interest.

Nonetheless, Griffith et al disclose sample 188 and culture medium 189 are mixed in a feed reservoir 185 (relied on as the immersion box) in proportions so as to provide an appropriate sample concentration. Culture medium containing a test substance is circulated by a pump 186 through a microscale tissue array 101 contained within a reactor housing 181 [see fig 7 and column 31 lines 19-25].

In addition, Dolecek et al disclose a flexible transparent doughnut-shaped bag that is configured to be filled with a medium [see 0061] and operable to be pressed against the region of interest.

Therefore, one skilled in the art at the time the invention was made would have been motivated to combine Kline with Griffith et al and Dolecek et al by using flexible transparent doughnut-shaped bag to contain the immersion medium and presses against the region of interest; because it can comply to the region of interest and allow the physician to see through.

Response to Arguments

6. Applicant's arguments with respect to claims 14 and 16-22 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that Kline doesn't teach illuminating human or animal tissue in vivo.

Kline discloses means for administering carbon dioxide and oxygen into the lung [see figs 1-4, 0042-0047] and lasers operating in the near infrared [see 0055] to illuminate the lung. Kline discloses laser diode spectrometry can be used for detection of more than one gas and can be used for determining the presence of various pathophysiological processes that are specific to certain disease states and diagnosing the presence of lung cancer [see 0026, 0057 and abstract].

As disclosed above, the lung is part of human or animal, therefore, Kline discloses animal or human tissue. Kline discloses measuring concentration of gases exhaled by a patient [see 0022-0024] and in vivo because the procedure is done with a live patient [see 00-420043].

Nonetheless, Liu et al is also used for the teaching of in vivo and human or animal tissue.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is

(571)270-3847. The examiner can normally be reached on Mon-Thu 8:30 AM to 7:00 PM (Off Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3777

/Tse Chen/

Supervisory Patent Examiner, Art Unit 3777